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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,257	12/21/2001	Peter Krulevitch	IL-10580	6642

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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,257	KRULEVITCH ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 July 2004 and 11 August 2004 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5, "said first mentioned member" lacks antecedent basis. Note claim 5 depends from claim 1 not claim 2. Claims 6-10 are indefinite in view of their dependencies from claim 5.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5, 6, 9-14 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Pourahmadi et al.(WO 99/33559).

With respect to claim 1, the reference of Pourahmadi et al. discloses a microfabricated biopsy and genetic analysis instrument that includes a cutter section and specimen chamber (103) located below the cutter section. See page 20, line 27, to page 21, line 10, which discloses that the opening of the specimen chamber (sample port, 103) can include a mesh that slices a tissue specimen. The instrument includes a specimen treatment section (including treatment chambers 107, 119, 122, 141) located adjacent the specimen chamber (103) and a PCR reaction chamber section that is integral or abuts the specimen treatment section. See page 12, lines 13-26, which discloses that the PCR reaction chamber (143) can be integral or separable relative to the sample treatment section of the instrument. With respect to the claim language "biopsy region" and "genetic region", in the absence of further positively recited structure to define these claim limitations, the section of the instrument including the sample port and sample treating chambers is considered to be the biopsy region and the section of the instrument including the reaction chamber (143) is considered to be the genetic region.

With respect to claims 5, and 6, the reference of Pourahmadi et al. discloses the use of microchannels (See Figure 2) to connect the sample chamber (103) with the PCR reaction chamber (143). Also the reference discloses the use of planar members, including glass, to form the device (See page 26, line 35, to page 27, line 28).

With respect to claim 9, the reference of Pourahmadi et al. discloses that the PCR reaction chamber (143) includes a heater (See page 12, lines 13-26).

With respect to claim 10, the reference of Pourahmadi et al. discloses an outlet (145) provided in communication with the PCR reaction chamber (143) through microchannels (See Figure 2).

With respect to claims 11, 12 and 18, as shown in Figure 2, the PCR reaction chamber has a cross-section or width that is greater than the chambers of the specimen treatment section.

With respect to claims 13, 14 and 17, the reference of Pourahmadi et al. discloses that the PCR reaction section (143) can be formed as a separate member or integral member (See page 12, lines 14-16).

With respect to claim 16, the PCR reaction chamber is capable of receiving a fluid or sample from the specimen treatment section.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 2-4, 7, 8, 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi et al.(WO 99/33559) in view of Krulevitch et al.(US 5,985,217 or US 6,319,474).

The reference of Pourahmadi et al. has been discussed above.

While the reference of Pourahmadi et al. discloses the use of mesh member for cutting or slicing a tissue sample, instant claims 2-4 and 15 differ by reciting that the cutter section includes a cutting edge with atomic sharpness.

The reference of Krulevitch et al. discloses that it is conventional in the art to integrate a tissue cutting structure into a microfluidic device. The device includes a first member (31) that includes a tapered opening with a cutting edge (35) with atomic sharpness. The cutting member or edge is provided over specimen receiving chamber (34). The reference also discloses that microchannels (40) for processing fluids can be provided in communication with the specimen

receiving chamber (34). The microchannels are provided on a separate member (32) bonded to the first member.

In view of this disclosure, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the mesh structure of the primary reference with the cutting device taught by the reference of Krulevitch et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result, cutting or slicing a tissue sample prior to introduction into a microfluidic device. The cutting device suggested by Krulevitch et al. would provide thinner samples than that of the primary reference, thus reducing the time to further process the tissue sample once within the microfluidic device.

With respect to claim 7, the reference of Krulevitch et al. discloses that the use of an additional inlet (45) and microchannel (40) for introduction of processing fluids is known in the art and would have been obvious for the known and expected result of providing additional fluids for processing the tissue slice prior to the cellular processing already discussed by the primary reference of Pourahmadi et al.

With respect to claim 8 and 19, the reference of Krulevitch et al. also discloses that it is known to optically view the tissue slice within the receiving chamber (See Figure 3C).

In view of this additional disclosure, it would have been obvious to one of ordinary skill in the art to further modify the primary reference of Pourahmadi et al. to include an optical analysis device as suggested by Krulevitch et al. for the known and expected result of providing an art recognized means for optically analyzing the tissue slice prior to further processing within the microfluidic device.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,985,217 in view of Pourahmadi et al.(WO 99/33559). Claims 1-15 of U.S. Patent 5,985,217 encompass a microfabricated biopsy/genetic analysis instrument, comprising: a cutter section, a specimen chamber located adjacent said cutter section, a specimen treatment section located adjacent said specimen chamber.

While the claims disclose that the device includes microchannels for delivering chemicals for treating the specimen, claims 1 and 16 differ by reciting that the device includes a PCR reaction chamber section "that is integral with said specimen treatment section or abuts" the specimen treatment chamber.

The reference of Pourahmadi et al. discloses that it is known in the art to combine microfabricated sample preparation device, including tissue slicing or cutting with microfabricated analyte detection and/or microfabricated polynucleotide amplification. The

reference of Pourahmadi et al. discloses a microfabricated biopsy and genetic analysis instrument that includes a cutter section and specimen chamber (103) located below the cutter section. See page 20, line 27, to page 21, line 10, which discloses that the opening of the specimen chamber (sample port, 103) can include a mesh that slices a tissue specimen. The instrument includes a specimen treatment section (including treatment chambers 107, 119, 122, 141) located adjacent the specimen chamber (103) and a PCR reaction chamber section that is integral or abuts the specimen treatment section. See page 12, lines 13-26, which discloses that the PCR reaction chamber (143) can be integral or separable relative to the sample treatment section of the instrument.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the tissue cutting device encompassed by the patented in place of the mesh material employed by the reference of Pourahmadi et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result, cutting or slicing a tissue sample prior to introduction into a microfluidic device while providing art recognized microfluidic structures for further processing and analysis of the tissue sample.

With respect to the claim language "biopsy region" and "genetic region", in the absence of further positively recited structure to define these claim limitations, the section of the instrument including the sample port and sample treating chambers is considered to be the biopsy region and the section of the instrument including the reaction chamber (143) is considered to be the genetic region.

With respect to claim 2, see patented claim 2.

With respect to claim 3, see patented claim 7.

With respect to claim 4, see patented claims 2-4.

With respect to claims 5, and 6, the reference of Pourahmadi et al. discloses the use of microchannels (See Figure 2) to connect the sample chamber (103) with the PCR reaction chamber (143). Also the reference discloses the use of planar members, including glass, to form the device (See page 26, line 35, to page 27, line 28).

With respect to claims 8 and 19, see patented claim 1.

With respect to claim 9, the reference of Pourahmadi et al. discloses that the PCR reaction chamber (143) includes a heater (See page 12, lines 13-26).

With respect to claim 10, the reference of Pourahmadi et al. discloses an outlet (145) provided in communication with the PCR reaction chamber (143) through microchannels (See Figure 2).

With respect to claims 11, 12 and 18, as shown in Figure 2, the PCR reaction chamber has a cross-section or width that is greater than the chambers of the specimen treatment section.

With respect to claim 15, see patented claims 6 and 7.

With respect to claims 13, 14 and 17, the reference of Pourahmadi et al. discloses that the PCR reaction section (143) can be formed as a separate member or integral member (See page 12, lines 14-16).

With respect to claim 16, the PCR reaction chamber is capable of receiving a fluid or sample from the specimen treatment section.

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11. Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,319,474 in view of Pourahmadi et al.(WO 99/33559). Claims 1-19 are obvious over claims 1-19 of patent '474 and the reference of Pourahmadi et al. for the same reasons as set forth with respect to the combination of Claims 1-15 of U.S. Patent '217 and Wilding et al. set forth above.

Response to Arguments

12. Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection including the reference of Pourahmadi et al.(WO 99/33559).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB